

ViraCHEK™

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FELINE LEUKEMIA VIRUS ANTIGEN TEST KIT

ViraCHEK™ | FeLV

ENGLISH

For the detection of Feline Leukemia Virus (FeLV) antigen in feline whole blood, serum, and plasma.

GENERAL INFORMATION AND INTENDED USES

The plastic wells contain antibodies directed against the FeLV group specific antigen, p27. A monoclonal antibody directed against p27 is labeled with the enzyme horseradish peroxidase (HRP). The specimen (whole blood, plasma or serum) is incubated simultaneously with the solid phase and enzyme-labeled antibodies. If present, p27 group specific antigen is bound to the antibody coated well and enzyme-linked antibody at the same time. Any free enzyme linked antibody is washed away and a chromogenic substrate is added. The development of a distinctly blue color specifically indicates the presence of FeLV. In the absence of FeLV, no color change will be observed.

ViraCHEK™/FeLV is highly specific, sensitive and simple to use. Test results for circulated antigen can be obtained in 10 minutes or less. Most cats initially become antigen positive within 2-3 weeks after virus exposure. Progressive infections will remain positive while regressive infections may revert to antigen negative 2-8 weeks, or more, later.

KIT COMPOSITION AND CONSERVATION

Contains materials sufficient to test 48 to 140 samples.

ITEM	REAGENT NATURE	VOLUME	RECONSTITUTION AND CONSERVATION
A	Anti-FeLV Antibody Coated Wells	3 sets of 4x12 wells	Ready to use.
CONTROL +	Positive Control; preserved with Gentamicin Sulfate and Amphotericin B	3.0 mL	Ready to use. Red Cap.
CONTROL -	Negative Control; preserved with Gentamicin Sulfate and Amphotericin B	3.0 mL	Ready to use. Gray Cap.
1	HRP Monoclonal Antibody Conjugate; preserved with Phenol and Microcide III	7.5 mL	Ready to use. Blue Cap.
2	Substrate Buffer	2 x 7.0 mL	Ready to use. Purple Cap.
	Well holder		

Store all reagents provided in the kit at 2 – 7 °C. Reagents should not be frozen.

REAGENTS REQUIRED TO PERFORM 48 TESTS

- a) 48 Anti-FeLV Antibody Coated Wells
- b) 1.0 mL Positive Control
- c) 1.0 mL Negative Control
- d) 2.5 mL Conjugate
- e) 1 Bottle Substrate Buffer

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- a) Marking Pen
- b) Deionized or distilled water or normal saline
- c) Wash Bottle
- d) Precision Pipettes
- e) Timer

WARNINGS TO THE USERS OF REAGENTS AND ANTIBODY COATED PLATES

- Handle all reagents and samples as biohazardous material. It is recommended to dispose reagents and contaminated material according to the applicable regulations.
- Wear suitable protective clothing.
- Irritating to skin and eyes. Keep all reagents away from skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- Take care not to contaminate any test reagents with samples or bacterial agents.
- The best results are achieved by following the protocols described below, using good, safe laboratory techniques.
- Do not use this kit or any of its contents after the expiration date and do not intermix components from different serial numbers.
- Use a separate pipette tip for each sample.
- Follow instructions exactly. Improper washing or contamination of reagents may produce nonspecific color development.
- Do not expose kit to direct sunlight.
- For veterinary use only.
- NEVER PIPETTE BY MOUTH. Harmful if swallowed.

NOTE: Allow all components to come to 21 – 25 °C before starting.

SAMPLE COLLECTION AND STORAGE

- Follow proper sample collection procedures.
- 50 µL (0.05 mL) of feline anticoagulated whole blood, plasma or serum is required.
- Harvest sample and store properly (up to seven days at 2 - 7 °C for serum and plasma, up to 24 hours for whole blood).
- For prolonged storage, serum and plasma samples should be kept frozen (-20 °C or colder).
- Test only good quality samples (i.e. avoid bacterial contamination, heavy hemolysis or lipemia). When in doubt, obtain a better quality sample.

FOR THE TEST PROCEDURE PLEASE SEE DETAILED INSTRUCTIONS IN THE BOTTOM PANEL (BELOW).

DANGER / DANGER / PELIGRO / PERICOLO / PERIGO / GEFAHR / NIEBEZPIECZEŃSTWO / อันตราย



Substrate Buffer: Danger. Causes serious eye irritation. May damage the unborn child. Harmful to aquatic life with long-lasting effects. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves / protective clothing / eye protection / face protection. Wash thoroughly after handling. Avoid release to the environment. If exposed or concerned: get medical advice / attention. **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: get medical advice / attention. Store locked up. Dispose of contents / container in accordance with local / regional / national / international regulations.

Tampón de substrat: Danger. Provoque une sévère irritation des yeux. Peut nuire au fœtus. Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme. Se procurer les instructions avant utilisation. Ne pas manipuler avant d'avoir lu et compris toutes les précautions de sécurité. Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage. Se laver soigneusement après manipulation. Éviter le rejet dans l'environnement. En cas d'exposition prouvée ou suspectée : consulter un médecin. EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. Si l'irritation oculaire persiste : consulter un médecin. Garder sous clé. Éliminer le contenu / récipient conformément à la réglementation locale / régionale / nationale / internationale en vigueur.

Tampón sustrato: Peligro. Provoca irritación ocular grave. Puede dañar al feto. Nocivo para los organismos acuáticos, con efectos nocivos duraderos. Pedir instrucciones especiales antes del uso. No manipular la sustancia antes de haber leído y comprendido todas las instrucciones de seguridad. Llevar guantes / prendas / gafas / máscara de protección. Lavarse tras la manipulación. Evitar su liberación al medio ambiente. En caso de exposición manifiesta o presunta: consultar a un médico. EN CASO DE CONTACTO CON LOS OJOS: adorar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir adarando. Si persiste la irritación ocular: consultar a un médico. Guardar bajo llave. Eliminar el contenido / el recipiente de conformidad con las normativas locales / regionales / nacionales / internacionales.

Tampone substrato: Pericolo. Provoca grave irritazione oculare. Può nuocere al feto. Nocivo per gli organismi acquatici con effetti di lunga durata. Procurarsi istruzioni specifiche prima dell'uso. Non manipolare prima di avere letto e compreso tutte le avvertenze. Indossare guanti/indumenti protettivi/Proteggere gli occhi/il viso. Lavare accuratamente dopo l'uso. Non disperdere nell'ambiente. In caso di esposizione o di possibile esposizione, consultare un medico. IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare. Se l'irritazione degli occhi persiste, consultare un medico. Conservare sotto chiave. Smaltire il prodotto / recipiente in conformità alle disposizioni locali / regionali / nazionali / internazionali.

Tampão de Substrato: Perigo. Provoca irritação ocular grave. Pode afetar o nascituro. Nocivo para os organismos aquáticos com efeitos duradouros. Pedir instruções específicas antes da utilização. Não manusear o produto antes de ler e perceber todas as precauções de segurança. Usar luvas de proteção / vestuário de proteção / proteção ocular / proteção facial. Lavar completamente após o manuseio. Evitar a liberação para o ambiente. Em caso de exposição ou suspeita de exposição: consultar um médico. SE ENTRAR EM CONTATO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contato, retire-as, se isso for possível. Continuar a enxaguar. Se a irritação degli occhi persiste, consultare un medico. Armazenar em local fechado a chave. Eliminar o conteúdo / recipiente de acordo com os regulamentos locais / regionais / nacionais / internacionais.

Substratpuffer: Gefahr. Verursacht schwere Augenreizung. Kann das Kind im Mutterleib schädigen. Schädlich für Wasserorganismen, mit langfristiger Wirkung. Vor Gebrauch besondere Anweisungen einholen. Vor Gebrauch alle Sicherheitshinweise lesen und verstehen. Schutzhandschuhe / Schutzkleidung / Augenschutz / Gesichtsschutz tragen. Nach Gebrauch gründlich waschen. Freisetzung in die Umwelt vermeiden. Bei Exposition oder falls betroffen: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen. BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser ausspülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen. Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen. Unter Verschluss aufbewahren. Inhalt/ Behälter gemäß lokalen / regionalen / nationalen / internationalen Vorschriften der Entsorgung zuführen.

Bufor substratem: Niebezpieczeństwo. Działa drażniąco na oczy. Może działać szkodliwie na dziecko w łonie matki. Działa szkodliwie na organizmy wodne, powodując długotrwałe skutki. Przed użyciem zapoznać się ze specjalnymi środkami ostrożności. Nie używać przed zapoznaniem się i zrozumieniem wszystkich środków bezpieczeństwa. Stosować rekawice ochronne/odzież ochronna/ochronę oczu/ochronę twarzy. Po użyciu dokładnie umyć. Unikać uwolnienia do środowiska. W przypadku narażenia lub styczności: zasięgnąć porady/zgłosić się pod opiekę lekarza. W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W przypadku utrzymywania się działania drażniącego na oczy: zasięgnąć porady/zgłosić się pod opiekę lekarza. Przechowywać pod zamknięciem. Zawartość / pojemnik usuwać zgodnie z przepisami lokalnymi / regionalnymi / krajowymi / międzynarodowymi.

สารละลายล้างตลับ อันตราย ทำให้ดวงตาระคายเคืองอย่างรุนแรง อาจเป็นอันตรายต่อเด็กในครรภ์ได้ เป็นอันตรายต่อชีวิตสัตว์น้ำ และมีผลกระทบต่อระบบยาว ขอคำแนะนำเฉพาะก่อนใช้งาน ห้ามจับจนกว่าจะได้อ่านและเข้าใจข้อควรระวังด้านความปลอดภัยทั้งหมดแล้ว ใส่ถุงมือป้องกัน/เสื้อผ้าป้องกัน/เครื่องป้องกันดวงตา/เครื่องป้องกันใบหน้า ล้างทำความสะอาดให้สะอาดหลังการสัมผัส หลีกเลี่ยงการปล่อยออกสู่สิ่งแวดล้อม หากสัมผัสหรือมีความกังวล กรุณาขอความช่วยเหลือทางการแพทย์ หากเข้าตา: ล้างด้วยน้ำเปล่าหลายๆ นาทีอย่างระมัดระวัง ถอดคอนแทคเลนส์ออก หากใส่อยู่และสามารถทำได้โดยง่าย ล้างต่อไปเรื่อย ๆ หากยังระคายเคืองต่อไป กรุณาขอความช่วยเหลือทางการแพทย์ จัดเก็บไว้ในที่ที่ปลอดภัย ห่างสัตว์/ภาชนะบรรจุตามข้อบังคับในท้องถิ่น/ภูมิภาค/ประเทศ/ระหว่างประเทศ

INTERPRETATION OF RESULTS

Controls:

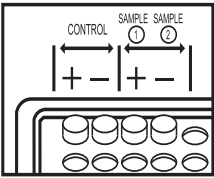
- POSITIVE control should be distinctly blue.
- NEGATIVE control should be completely clear.

Samples:

- POSITIVE samples will be blue. Color intensity will vary with level of FeLV antigen present.
- NEGATIVE samples will be clear. Compare directly with the negative control against a white background.

NOTES

- When mixing well contents in Steps 4 and 11, tap microplate rapidly for a full 15 seconds.
- Washing is the most important step. Microwells cannot be overwashed.** Underwashing will result in nonspecific blue color development in the negative control and sample wells.
- Remember! Use saline as the wash solution with whole blood samples.
- Read results at 5 minutes. If no color is seen at 5 minutes, the sample is negative.



SYMBOL DESCRIPTIONS

	Use by Date (expiration date)		Authorized Representative in the European Community
	Batch Code		Consult Instructions for Use
	Serial Number		In Vitro diagnostic medical device
	Temperature limitations (storage temperature range)		Manufacturer

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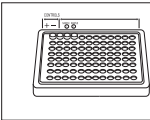
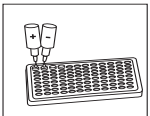
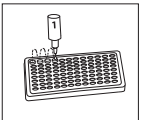
VLN/PCN 190/5028.00

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TEST PROCEDURE / PROCÉDURE DE TEST

STEP/ ÉTAPE	NOTES/REMARQUES	
SET UP AND SAMPLE INCUBATION / DISPOSITION ET INCUBATION DES ÉCHANTILLONS		
1)	Remove and place in well holder one well for Positive Control, one well for Negative Control, and one well for each sample. Leave the wells attached to each other. Sortir le portoir pour puits et y placer un puits pour le contrôle positif, un puits pour le contrôle négatif et un puits pour chaque échantillon. Ne pas séparer les puits.	
2)	Add 1 drop of Positive Control (Red Cap) into the first well. Add 1 drop of Negative Control (Gray Cap) into the second well. Ajouter 1 goutte de contrôle positif (bouchon rouge) dans le premier puits. Ajouter 1 goutte de contrôle négatif (bouchon gris) dans le deuxième puits.	
3)	Pipette 50 µL (0.05 mL) of sample (anticoagulated whole blood, plasma or serum) into the next well following the controls. Repeat for each additional sample into subsequent wells. One well is used for each sample. Pipeter 50 µL (0.05 mL) d'échantillon (sang total, plasma ou sérum anticoagulés) dans le puits suivant les contrôles. Répéter la procédure pour chaque échantillon supplémentaire dans les puits suivants. Utiliser un puits pour chaque échantillon.	
CONJUGATE / CONJUGUÉ		
4)	Add 1 drop of Conjugate (Bottle 1 - Blue Cap) into each well. Gently tap the well holder (without splashing) for 15 seconds to mix. Ajouter 1 goutte de conjugué (flacon 1 - bouchon bleu) dans chaque puits. Tapoter doucement le portoir pour puits (sans provoquer d'éclaboussures) pendant 15 secondes afin de bien mélanger.	
5)	Incubate for 5 minutes at 21 – 25 °C. / Incuber pendant 5 minutes entre 21 et 25 °C.	